GOVERNMENT OF ANDHRA PRADESH
ABSTRACT

HM&FW Dept - Drugs Control Administration – Standard Operating Procedure / Guidelines in taking action for violation of conditions of Sales Licenses under Drugs & Cosmetics Rules, 1945 by the District Sales Licensing Authorities – Permission – Accorded – Orders – Issued.

HEALTH, MEDICAL & FAMILY WELFARE (I.1) DEPARTMENT

G.O.MS.No. 21 **Dated: 24-02-2021.**

Read:-

From the Director General, Drugs and Copyrights, Drugs ControlAdministration,A.P.,Guntur,Rc.No:HMF07-19024/29/ 2020-ACC-DCA, Dt: 20-07-2020 & 27-10-2020.

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ORDER:

In the reference read above, the Director General, Drugs and Copyrights, Drugs Control Administration, A.P., Guntur has furnished Standard Operating Procedure (SoP) / Guidelines in taking action for violation of conditions of Sales Licenses under Drugs & Cosmetics Rules, 1945 by the District Sales Licensing Authorities in the State of Andhra Pradesh and requested the Government to accord permission to adopt them in order to achieve the uniformity in the implementation of the provisions of the Drugs & Cosmetics Rules, 1945.

2. Government after careful examination of the matter, hereby accord permission to the Director General, Drugs and Copyrights, Drugs Control Administration, A.P.,Guntur to adopt Standard Operating Procedure (SoP)/Guidelines in taking action for violation of conditions of Sales Licenses under Drugs & Cosmetics Rules, 1945 by the District Sales Licensing Authorities in the State of Andhra Pradesh in order to achieve the uniformity in the implementation of the provisions of the Drugs & Cosmetics Rules, 1945 to ensure the availability of the safe and efficacious drugs to the public.

3. The Standard Operating Procedure (SoP) / Guidelines for taking action on Wholesale & Retail Licensees for violation of condition of Licenses under Drugs & Cosmetics Rules, 1945 is appended as Annexure to this order.

4. The Director General, Drugs and Copyrights, Drugs Control Administration, A.P., Guntur shall take necessary follow-up action in this matter.

(BY ORDER AND IN THE NAME OF THE GOVERNER OF ANDHRA PRADESH)

ANIL KUMAR SINGHAL
PRINCIPAL SECRETARY TO GOVERNMENT

To
The Director General, Drugs and Copyrights,
Drugs Control Administration, A.P., Guntur
Copy to:
P.S. to Dy.Chief Minister(HFW&ME)
P.S. to Prl. Secretary to Govt., HM&FW Dept.
Sf/Sc.

//FORWARDED :: BY ORDER//

SECTION OFFICER

contd..to Annexure

ANNEXURE TO G.O.Ms.No.21, HM&FW(I.1)Dept., Dt:24.02.2021

	SOP's / Guidelines for taking action on Wholesale & Retail Licensees for violation of condition of Licenses under Drugs and Cosmetics Rules, 1945			
			Suspension/Cancellation of Licenses for Violations observed (Days)	
S.No	Rule	Description of Rule/ condition of License in brief	1st Time	Next Time
1	65	Display of License in a prominent place in the premises open to the public	1	2
2	65(2)	Any drug supplied on the prescription of a Registered Medical Practitioner shall be effected only by or under the personal supervision of a registered pharmacist	7	15
3	65(3)(1)	The supply of any drug (other than those specified in Schedule X) on a prescription of a Registered Medical Practitioner shall be recorded at the time of supply in a prescription register specially maintained for the purpose as mentioned in the said Rule	3	7
4	65(4)(1)	The supply by retail, otherwise than on a prescription of a drug specified in Schedule C shall be recorded Register or cash or credit memo book as mentioned in the said Rule	1	2
5	65(4)(3)(i)	The supply by retail of any drug shall be made against a cash or credit memo as mentioned in the said Rule	7	15
6	65(4)(3)(ii)	Carbon copies of cash or credit memos shall be maintained by the licensee as record.	7	15
7	65(4)(4)	Records of purchase of a drug intended for sale or sold by retail shall be maintained as mentioned in the said Rule	7	15
8	65(5)(1)	The supply of a drug by wholesale shall be made against a cash or credit memo as mentioned in the said Rule	7	15
9	65(5)(2)	Carbon copies of cash or credit memos shall be preserved as records for a period of three years from the date of the sale of the drug.	7	15

10	65(5)(3)	Records of purchase of a drug intended for resale or sold by wholesale shall be maintained as mentioned in the said Rule	7	15
11	65(6)	The licensee shall produce for inspection by an Inspector appointed under the Act on demand all registers and records maintained under these rules	7	15
12	65(7)	All registers and records maintained under these rules shall be preserved for a period of not less than two years from the date of the last entry therein	7	15
13	65(9)(a)	Substances specified in Schedule H and Schedule H1 or Schedule X shall not be sold by retail except on and in accordance with the prescription of a Registered Medical Practitioner and in the case of substances specified in Schedule X, the prescriptions shall be in duplicate, one copy of which shall be retained by the licensee for a period of two years	7	15
14	65(9)(b)	The supply of drugs specified in Schedule H and Schedule H1 or Schedule X to Registered Medical Practitioners, Hospitals, Dispensaries and Nursing Homes shall be made only against the signed order in writing which shall be preserved by the licensee for a period of two years	3	7
15	65(11)	Dispensing a prescription containing Schedule H and Schedule H1 and Schedule X drugs shall comply with the requirements as mentioned in the said Rule	3	7
16	65(11A)	No person dispensing a prescription containing substances specified in Schedule H and Schedule H1 or X may supply any other preparation, whether containing the same substances or not in lieu thereof	3	7
17	65(12)	Substances specified in Schedule X kept in retail shop or premises as mentioned in the said Rule	3	7
18	65(15)	Description of the licensee shall be displayed as mentioned in the said Rule	1	2
19	65(17)	No drug shall be stocked by the licensee in violation of any statement or direction recorded on such container, label or wrapper. Ex: Stocking of Drugs requiring Cold storage at room temperature.	7	15

20	65(17)	No drug shall be stocked by the licensee after the date of expiration of potency or in violation of any statement or direction recorded on such container, label or wrapper.	7	15
21	65(19)	The supply by retail of any drug in a container other than the one in which the manufacturer has marketed the drug, shall be made only under the direct supervision of Registered Pharmacist as mentioned in the said Rule.	3	7
22	65(20)	The medicines for treatment of animals kept in a retail shop or premises shall be labelled with the words "Not for human use—for treatment of animals only" and shall be stored separately as mentioned in the said Rule.	1	2
23	65(21)(a)	The supply of drugs specified in Schedule X shall be recorded in Register specifically maintained as detailed in the said Rule	7	15
24	65	Conditions of Licences in Forms 20, 20A, 20B, 20F, 20G, 21 and 21B :		
25	65	1. Reporting of change of Qualified staff to the Licensing Authority within one month (Form-20, 21, 20F)	3	7
26	65	2. Forward the copies of invoices of sales to Licensing Authority (Form-20G)	1	2
Note: While the above guidelines are advisory in nature, the Licensing Authority may in his discretion resort to cancellation of license if in case the licensee is found to be a habitual violator or recurrent violations are noticed or the violations are grave.				

violations of Serious Nature				
			Suspension of Licenses for Violations observed (Days)	
S.No	**Rule**	**Description of Rule/ condition of License in brief**	**1st Time**	**Next Time**
1	65(18)	Drug intended for distribution to the Government Institutions found stored	Cancellation & Prosecution	-
2	65(18)	Drug intended for distribution to the medical profession as free sample found stored	30	Cancellation & Prosecution

3	65(2)	Any drug supplied on the prescription of a Registered Medical Practitioner shall be effected only by or under the personal supervision of a registered pharmacist and if the approved RP is found working/employed simultaneously in any other place or role full time.	30	Cancellation & Prosecution
4	65(4)(3)(i)	The supply by retail of any drug shall be made against a cash or credit memo as mentioned in the said Rule in case of NRx Drugs	Suspension of Licenses in respect of NRx Drugs for 90 days	Cancellation & Prosecution
5	65(5)(1)	The supply of a drug by wholesale shall be made against a cash or credit memo as mentioned in the said Rule in case of NRx Drugs	Suspension of Licenses in respect of NRx Drugs for 90 days	Cancellation & Prosecution
6	65	No drug shall be sold unless such drug is purchased under cash/credit memo from a duly licensed dealer or a manufacturer (clandestine procurement from unauthorised source) (Forms-20, 21, 20B, 21B, 20G,20F)	30	Cancellation/ Prosecution
7	65	No sale of any drug shall be made to a person/firm not holding the requisite license (Form-20B, 21B, 20G)- subject to the specific exemptions/conditions mentioned therein. (clandestine sale). Ex: Sale of Drugs to Unqualified practitioners etc.	30	Cancellation/ Prosecution
8	65(17)	No drug shall be **sold** by the licensee after the date of expiration of potency or in violation of any statement or direction recorded on such container, label or wrapper. Ex: Sale of MTP Kits against the directions of label, Sale of Blood Bags to Diagnostic Labs/Hospitals	30	Cancellation / Prosecution

ANIL KUMAR SINGHAL
PRINCIPAL SECRETARY TO GOVERNMENT